Accredited Person Inspection Program Rating Criteria Cover Sheet

Background

Each of the 8 elements was assigned a weight agreed upon by the Food and Drug Administration's (FDA's) Third Party Recognition Board (TPRB) in conjunction with the Center for Devices and Radiological Health (CDRH) Senior Staff. Each applicant's package will be assessed by the TPRB. After assessment by the TPRB each of the 8 elements will be voted a "quality level" score from 0-4; **0 = Unsatisfactory, 2= Satisfactory, and 4= Exceeds.**

Each element has been assigned a weight of 5, 15 or 20. The weight of the element is based on how essential the information in the element is, in determining if the applicant is suitable to perform Quality System/Good Manufacturing Practices (QS/GMP) inspections on behalf of FDA.

Quality Level Score x Weight = Element Score. The 8 element scores will be totaled to yield an "Application Rating" (**maximum rating attainable is 400**). TPRB will rank the applications (highest application rating first). MDUFMA requires that no more then 15 persons be accredited during the 12 months that follows the publication of this guidance.

Definition of Acceptance Level Score

Exceeds = (4) A rating of "Exceeds" is determined for an element when all items within an element are Satisfactory and at least 50% are substantially above the standard.

Satisfactory = (2) A rating of "Satisfactory" is determined for an element when processes for adequately accomplishing the requirements are fully explained and supporting documentation confirms the process.

Unsatisfactory = (0) A rating of "unsatisfactory" is determined for an element when the process for accomplishing the requirement is inadequate, not clearly and fully explained or supporting documentation is missing/incomplete.

Quality Level Score x Weight= Element Score

Shaded Areas to be Completed by TPRB

ACCREDITED PERSON INSPECTION PROGRAM RATING CRITERIA

Checklist for evaluating application to determine if they meet FDA's criteria for conducting QS/GMP FDA inspections

Document Type: Original ☐ Supplement ☐

Applicant Number: _____ Applicant: _____

Value ____ x Weight __15__ = Element Score _____				
1.	**ADMINISTRATIVE INFORMATION**	**Rating** **U-S-E**	**Where found in AP Guidance**	**AP applicant should identify where process, procedures, or documentation is found in AP application**
	AP applicant has provided the following administrative information: 1. Application in English 2. Name and Address of Applicant 3. Contact Person (phone # and E-mail) 4. Most Responsible Person for the AP 5. Most Responsible Person for the Parent Organization (if applicable)		**See IV. B. 1. "Administrative Information" Pages 23 - 24**	

1.	**ADMINISTRATIVE INFORMATION** **(cont.)**	**Rating** **U-S-E**	**Where found in AP Guidance**	**AP applicant should identify where process, procedures, or documentation is found in AP application**
	AP applicant has provided the following administrative information: 6. Brief description of applicant including: • AP organizational chart identifying size of organization (number of employees) and relationship with any affiliates as well as any parent organization • documentation which clearly shows the authority, responsibility and reporting structure of all the individuals within the AP organization • number of employees available for the AP Inspection process and evidence that the AP applicant has **resources to conduct AP inspections in a competent manner.** • number of years in operation • nature of work (e.g. testing, certification laboratory, Conformity Assessment Body, etc.) 7. Is the AP applicant certified, accredited or recognized by a foreign country? State status of recognition. 8. Is the AP applicant accredited to assess quality systems by any registrar(s). Please specify. 9. Scope of Work – Activities for which the AP seeks accreditation.		**See IV. B. 1. "Administrative Information" Pages 23 - 24**	

Value ____ x Weight __20__ = Element Score _____				
2	**PREVENTION OF CONFLICT OF INTEREST**	**U-S-E**	**Where found in Guidance**	**AP applicant should identify where process, procedures, or documentation is found in AP application**
2.1	a. Written statement providing information on ownership, operation, and control of the applicant and its parent organization, if applicable, sufficient to assess its degree of independence from entities regulated under the act. b. Statement fully describing all sources of income c. Documentation clearly identifying the applicant's **legal status.**		**See IV. B. 2. "Prevention of Conflict of Interest" Pages 24 - 25**	
2.2	Policy statement that, at a minimum states: a. the AP applicant is not a Federal government entity b. the AP applicant is not owned, operated or controlled by a manufacturer, supplier, or vendor of articles regulated under the act. c. the AP applicant has no organizational, material, or financial affiliation (including a consultative affiliation) with a manufacturer, supplier, or vendor of articles regulated under the act. d. the AP applicant is not engaged in the design, manufacture, promotion or sale of articles regulated under the act or the authorized representative of any of those parties e. the AP applicant is impartial and does not charge fees contingent or based upon results of the AP inspections f. the AP applicant holds all employees, including contractors to the same coi standards		**See III. G. "What Qualifications are Necessary to Become an Accredited Person" Pages 12 - 13**	

2	**PREVENTION OF CONFLICT OF INTEREST** **(cont.)**	U-S-E	Where found in Guidance	AP applicant should identify where process, procedures, or documentation is found in AP application
2.3	Policy statement that at a minimum states: a. employees of the AP applicant involved in the inspection process do not engage in the design, manufacture, promotion or sale of articles regulated under the act. b. employees of the AP applicant involved in the inspection process do not provide consulting services to any organization regulated under the act. c. employees of the AP applicant involved in the inspection process, as well as their spouse and minor children do not own stock or have any financial interest in any manufacturer, supplier, or vendor of articles regulated under the act. d. employees of the AP applicant involved in the inspection process will not participate in an inspection of a firm in which they have performed prior assessments within the last 12 months e. employees of the AP applicant involved in the inspection process have not been employed by the firm being inspected within the last 12 months		**See III. H. 3. "How Can I Address these Qualifications in My Application to FDA" Page 15**	

2	**PREVENTION OF CONFLICT OF INTEREST** **(cont.)**	U-S-E	Where found in Guidance	AP applicant should identify where process, procedures, or documentation is found in AP application
2.4	Procedures to ensure that: a. there is a written COI declaration stating that there is no conflict of interest on the part of its regular or contract employees; that is, before each AP inspection those employees working on that inspection will declare in writing that they are free of any conflict of interest (attach copy of the COI declaration) b. there is no use of any officer or employee who has a financial conflict and the AP will annually make available to the public the extent to which the AP complies with its COI requirements c. employees (including contractors) with conflicts noted on the COI declaration will be disqualified from the review d. employees (including contractors) are aware that they must report any changes to their COI declarations to their supervisor as soon as the employee is aware of the changes e. the AP applicant will handle any complaints promptly and resolve all cases where conflicts are suspected or proven f. COI declarations as well as any conflict resolutions are made part of the official inspection file g. COI training is provided to all employees including contractors to ensure compliance with AP applicant's written COI policies and procedures		**See III. G. 5. "What Qualifications are Necessary to Become an Accredited Person?" Page 13** **See IV. B. 8. "Certification Agreement Statement" Page 28**	

Value ____ x Weight __20__ = Element Score _____				
3	**TECHNICAL COMPETENCE**	**U-S-E**	**Where found in Guidance**	**AP applicant should identify where process, procedures, or documentation is found in AP application**
3.1	Procedures to ensure that AP inspections are performed by competent and qualified personnel.		**See IV. B. 3. "Technical Competence" Pages 25 - 26**	
3.2	Procedures to ensure personnel involved in the AP inspection process have **satisfactory knowledge** of the United States (U.S.) FDA laws and **regulations** for medical devices, meet educational requirements, and have adequate experience in their area of competence.		**See above**	
3.3	Copy of **educational requirements** for AP inspectors? *The minimum education will generally be equivalent to a 4 year college/university degree in the U.S., including a minimum of 30 semester hours in one or a combination of the following: biological sciences, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, or related scientific fields that provide knowledge directly related to FDA consumer safety officer work.*		**See above**	

3	**TECHNICAL COMPETENCE** **(cont.)**	U-S-E	Where found in Guidance	AP applicant should identify where process, procedures, or documentation is found in AP application
3.4	Procedures to ensure that at least one member of an assessment team is trained and/or experienced in each of the following skills that is relevant to the assessment being made: 1. US FDA regulatory requirements for medical devices 2. US FDA policies and procedures for inspecting manufacturers of medical devices, including applicable compliance programs, and those sections of the *Investigations Operations Manual*, Compliance Policy Guides, and Regulatory Procedures Manual that are applicable to inspections/inspections in general and medical devices specifically 3. the **production methods, process validation** and the test and verification procedures applicable to the various types of medical devices subject to the inspection. 4. **design documentation** to determine that all aspects of the design control and development activity are in compliance with the requirements of the Quality System Regulation, 21 Code of Federal Regulations Section 820.30 5. for sterile medical devices, microbiological assessment, including validation and routine control of sterilization processes, and environmental control 6. general **principles for inspections**, the assessment and evaluation of quality systems, an investigative interviewing		**See III. H. 1. "Personnel" Pages 13 – 14** **See IV. B. 3 "Technical Competence" Pages 25 - 26**	

3	**TECHNICAL COMPETENCE** **(cont.)**	U-S-E	Where found in Guidance	AP applicant should identify where process, procedures, or documentation is found in AP application
3.5	Procedures to ensure that the inspection team is able to recognize, collect, and identify appropriate nonconformities to support assessments and evaluations of the manufacturer's level of conformance with US FDA regulatory requirements for medical devices.		**See III. H. 1. "Personnel" Pages 13 - 14**	
3.6	Procedures to ensure that AP inspectors are able to communicate verbally so as to clearly explain to the manufacturer: (1) the purpose and scope of the inspection; (2) any nonconformities identified; and (3) respond appropriately to questions asked by the manufacturer.		**See above.**	
3.7	Documentation that AP inspectors are able to report the findings of the inspection in written English in accordance with a **report format** specified by FDA.		**See above.**	
3.8	Evidence that personnel involved in inspecting quality systems are qualified in accordance with **ISO 10011**-2 or GHTF Study Group 4 documents.		**See above.**	
3.9	Evidence that management of quality systems assessments is in accordance with ISO 10011-3 or GHTF Study Group 4 documents.		**See above.**	
3.10	Copies of CVs for all personnel involved in the inspection process. CVs should include documentation addressing knowledge, education, training, skills, abilities and experience for all personnel involved in the AP inspectional process.		**See above.**	
3.11	Copy of the **training plan** that addresses the development of knowledge, skills, and abilities to perform AP inspections in a competent and consistent manner.		**See IV. B. 3. "Technical Competence" Pages 25 - 26**	

3	**TECHNICAL COMPETENCE** **(cont.)**	U-S-E	Where found in Guidance	AP applicant should identify where process, procedures, or documentation is found in AP application
3.12	Procedures to ensure that **records are** available to demonstrate that personnel have the appropriate **experience** and have received appropriate **training** relevant to the applicant's planned inspection activities.		**See above.**	
3.13	**Records** for each AP inspector include, at a minimum, the following information? ❑ name of inspector ❑ designated areas of competence and responsibility ❑ educational and professional qualifications ❑ work experience relevant to the activities being performed ❑ details of training received related to assessment activities, including training in the US FDA laws and regulations for medical devices identified in the Scope, and relevant standards, policies, and procedures		**See above.**	
3.14	Description of the management structure and supervision of the AP inspectors including any contractors involved in the inspectional process.		**See above.**	

Value ____ x Weight __5__ = Element Score _____				
4	**RESOURCES**	**U-S-E**	**Where found in Guidance**	**AP applicant should identify where process, procedures, or documentation is found in AP application**
4.1	A statement that appropriate references (e.g., FD&C Act, regulations, statutes, laws, applicable compliance programs, Regulatory Procedures Manual, Inspectional Operations Manual, Compliance Policy Guides, etc.) are available to enable inspectors to carry out inspections effectively.		**See III. H. 2. "Infra-structure" Page 14** **See IV. B. 4. "Resources" Page 26**	
4.2	A statement that buildings and resources (e.g., computer system with a modem, independent facsimile machine, security/safeguards for protecting any commercial, trade secrets and confidential information, etc.) that enable the applicant to perform the technical and administrative tasks connected with auditing.		**See above.**	

Value ____ x Weight __5__ = Element Score _____				
5	**CONFIDENTIALITY**	**U-S-E**	**Where found in Guidance**	**AP applicant should identify where process, procedures, or documentation is found in AP application**
5.1	Procedures to ensure **confidentiality** of all information obtained in the course of conducting AP inspections.		**See III. G. "General Require-ments" Item 5 iii - v Page 13** **See IV. B. 5. "Confidential-ity" Page 27**	
5.2	Procedures to ensure that no details, records, results, or information of any kind are disclosed to any other party except the US Food and Drug Administration, and the firm inspected.		**See above.**	
5.3	Procedures that the AP applicant uses to inform its personnel, including contractors of its confidentiality requirements (e.g. staff may sign a declaration not to divulge any information gained through the inspection process)		**See above.**	

Value ____ x Weight __15__ = Element Score _____				
6	**CONTRACTORS –** ***This element is applicable unless the applicant states that no contractors will be used for FDA inspectional work. Applicants not using contractors will receive element score of 60.***	**U-S-E**	**Where found in Guidance**	**AP applicant should identify where process, procedures, or documentation is found in AP application**
6.1	Procedures to ensure that contractors and their personnel conform to the same requirements (e.g. education, training, experience, and technical competence) that would apply to the AP and its personnel.		**See III. H. 3. "Prevention of Conflict of Interest" Pages 15 - 16** **See IV. B. 6. "Contrac-tors" Page 27**	
6.2	Procedures to ensure that the applicant will not subcontract the responsibility for supervising the inspectional process or reviewing the inspection reports.		**See above.**	
6.3	Procedures to ensure that when an AP applicant subcontract those parts of the inspection that require specialized knowledge, the AP applicant will possess sufficient knowledge to exert supervisory control over the contractor so that the final decision rest with the AP applicant.		**See above.**	
6.4	Copy of an agreement between the applicant and the contractor reflecting obligations, including confidentiality and the provision of access to records for the U.S. FDA. The agreement should include:		**See above.**	
6.4.1	A requirement that the contractor **certify conformance** with the conflict of interest requirements.		**See above.**	
6.4.2	A prohibition against contractors further subcontracting their duties.		**See above.**	

6	**CONTRACTORS** – ***This element is applicable unless the applicant states that no contractors will be used for FDA inspectional work. Applicants not using contractors will receive element score of 90.*** **(cont.)**	**U-S-E**	**Where found in Guidance**	**AP applicant should identify where process, procedures, or documentation is found in AP application**
6.5	Documentation that subcontracted activities are carried out according to **detailed documented procedures** which are the same as, or judged by the applicant to be equivalent to, those followed by the applicant when auditing for conformance with US FDA regulatory requirements for medical devices.		**See III. H. 3. "Prevention of Conflict of Interest" Pages 15 - 16** **See IV. B. 6. "Contrac-tors" Page 27**	
6.6	Written policies and procedures for maintaining a current **register of** all **contractors**, and a copy of the register		**See above.**	

Value ____ x Weight __15__ = Element Score _____				
7	**QUALITY SYSTEM OF THE APPLICANT**	**U-S-E**	**Where found in AP Guidance**	**AP applicant should identify where process, procedures, or documentation is found in AP application**
7.1	Documentation The AP applicant's established procedures and records, which demonstrate its compliance with U.S. FDA policies and procedures relevant to AP inspections. Copies of policies and procedures the AP applicant follows to control quality system documentation. This includes procedures to assure that a current version of all AP inspection-related SOPs are available at all locations performing work for the AP.		**See IV. B. 7. "Accredited Person Quality System" Page 28**	
7.1.1	AP applicant's documentation includes at least the following: Records to support the evaluation, the assessment, and conclusions about the manufacturer's compliance with the regulatory requirements of the US FDA for medical devices.		**See above.**	
7.2	The AP applicant's policies and procedures to ensure that the defined quality system **procedures** are **implemented** effectively (e.g., internal inspections)		**See above.**	

Value ____ x Weight __5__ = Element Score _____				
8	**CERTIFICATION/AGREEMENT STATEMENT**	**U-S-E**	**Where found in Guidance**	**AP applicant should identify where process, procedures, or documentation is found in AP application**
8.1	Is there a statement, signed by the most responsible individual at the applicant, certifying/ agreeing that a. the AP applicant has appropriate policies and procedures to meet FDA's COI provisions, has the appropriate staff and procedures to ensure technical competence for conducting inspections under section 704(g) of the Act and has the quality system in place to ensure acceptable and consistent inspections b. any contractor that the AP applicant uses or may use in the future will be held to the same standards as those required by it regular employees c. the AP applicant consents to FDA inspection and copying of all records, correspondence and other materials relating to any inspection conducted by the AP under this program, including records on personnel, education, training, skills, and experience and all documentation on prevention of COI d. the AP applicant will strictly preserve and protect the confidentiality of all information provided by any manufacturer or by FDA		**See IV. B. 8. "Certification Agreement Statement" Page 28**	

TOTAL ELEMENT SCORE: _____

Conclusion:

Applicant: Approved ☐ Disapproved ☐

Date of Review:

Name of Rating Board Member(s):